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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/397,110 09/16/99 MOORE N

HM22/1130

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EXAMINER

PORTNER, V

ART UNIT

PAPER NUMBER

1645

4

DATE MAILED:

11/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/397,110

Applicant(s)

Moore et al

Examiner

Portner

Group Art Unit
1645

☒ Responsive to communication(s) filed on Sep 16, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-30 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-30 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-30 are pending.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1,3-6 , drawn to methods of obtaining a C-polysaccharide antigen using acid/base neutralization methods of extraction, classified in class 536, subclass 124.
- II. Claims 2, drawn to C-polysaccharide antigen, classified in class 536 , subclass 123.1.
- III. Claims 7 is, drawn to methods of affinity purifying antibodies, classified in class 530, subclass 389.5.
- IV. Claim 8, drawn to antibodies specific to C-polysaccharide, classified in class 530, subclass 388.4.
- V. Claims 10-19 are, drawn to methods of assaying for the presence of S.pneumonia or C-polysaccharide using extracted bacterial antigen to affinity purify antibodies and assaying by any immunoassay method of detection, classified in class 435, subclass 7.34.
- VI. Claims 20-30, drawn to an assay device and method of using the assay device to detect the presence of

S.pneumoniae or C-polysaccharide cell wall antigen,
classified in class 436, subclass 535.

VII. Claim 9 is, drawn to a chromatographic column to which
is immobilized C-polysaccharide, classified in class
422, subclass 70.

2. Inventions I and II are related as process of making and
product made. The inventions are distinct if either or both of
the following can be shown: (1) that the process as claimed can
be used to make other and materially different product or (2)
that the product as claimed can be made by another and materially
different process (MPEP § 806.05(f)). In the instant case that
the product as claimed can be made by another and materially
different process, wherein the polysaccharide has been purified
by methods that result in less than 10% protein by methods known
in the art (see Havas et al, 1984, reference being made of
record).

3. Inventions II and III are related as product and process of
use. The inventions can be shown to be distinct if either or
both of the following can be shown: (1) the process for using the
product as claimed can be practiced with another materially
different product or (2) the product as claimed can be used in a
materially different process of using that product (MPEP
§ 806.05(h)). In the instant case the product as claimed can be

used in a materially different process of using that product, wherein the polysaccharide antigen is useful in the induction of antibodies, in methods of detecting diagnostic antibodies for diagnosis of infection, in the production process of producing monoclonal antibodies and in the production of molecular image polymers.

4. Inventions III and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case that the product as claimed can be made by another and materially different process, wherein the antibodies may be either monoclonal or polyclonal antibodies that are monospecific to C-polysaccharide antigen that contains less than 10% protein, and monoclonal antibodies would be monospecific to C-polysaccharide without the need for affinity purification.

Monoclonal antibodies to C-polysaccharide are monospecific and would not contain antibodies to any proteins. Gillespie et al (1994) produced a monoclonal antibody to *S.pneumoniae* C-polysaccharide which is a product that was produced by a materially different process and would meet the claimed invention of Group 8.

5. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the antibodies are useful in the affinity purification of antigen, in methods of detecting infection, in methods of producing anti-idiotypic antibodies for therapy and in the production of molecular image polymers.

6. Inventions VI and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because:

a. The combination of Group VI does not require the use of reagents for extraction of a culture of *S.pneumoniae* as required in Group V.

b. The subcombination defined by Group V has separate utility such as using the antibodies to detect infection without the use of a chromatographic device with zones. Immuno-precipitation assays, enzyme-linked immunosorbant assays, as well as homogenous nephelometric assays may be used. The method of detection may be any method and the immunochromatographic methods recited in dependent claims 17-19 do not require the structural components of the device defined in Group VI.

7. Inventions VII and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group VII can be used to identify and purify receptors from mammalian cell surfaces based upon bacterial polysaccharide affinity binding (see Sundberg-Kovamees et al abstract (1996) being made of record), as well as can be used to purify antibodies.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the search required for each of Groups I-IV differs and have been recognized as divergent subject

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matter, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

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The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

November 27, 2000

L. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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